

April 23, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 03-15

Tyra S. Wisecup
Compliance Officer
Food and Drug Administration
Minneapolis District Office
212 Third Avenue South
Minneapolis, MN 55401

Dear Ms. Wisecup:

We have received the letter from your department dated April 8th, and received on April 18st as we were out of town. Each portion of the letter will be addressed in the order written.

7-Grain Herb Bread

“Rich in Fiber, it also contains over 300 anti-carcinogenic compounds” has been removed from the Internet site.

A copy of our 7-Grain Herb Bread label is enclosed and you will see that it has NO statement that antioxidants “help prevent...degenerative diseases of all types” on the label. Perhaps that general statement was previously on the side of the bag but if so, it has been removed and replaced with “Excellence in Taste and Nutrition”.

- Regarding the calorie content, total fat and fiber content, we will resubmit samples of our product to XXXX Labs for analysis, adjusting anything necessary upon the next printing of our labels. A copy of the Lab report and label will be forwarded to you. Our present supply of labels should be used up by November, 2003.
- Regarding 225 mg of Omega-3 on the label. A copy of the XXXX Lab report is enclosed showing the amount of Omega-3 is correct as stated. We wonder if perhaps the tests were for fish oils? Our source of Omega-3 is from the ground flaxseed, which has been tested many times by independent analytical laboratories.

Right Wheat Whole Grain Bread

- Regarding the calorie content, total fat, fiber and protein content, we will resubmit samples of our product to XXXX Labs for analysis, adjusting anything necessary upon the next printing of our labels. A copy of the lab report and label will be forwarded to you. Our present supply of labels should be used up by November, 2003.

- Regarding the 175-mg of Omega-3, please see the enclosed XXXX Labs report showing the listed Omega-3 is correct according to their analysis.

Multi-Grain Stay Trim Bread

The statement on the side of the label “Antioxidants ...help prevent...degenerative diseases of all types” will be dropped with the next printing of the labels.

- Regarding the calorie content, total fat and fiber content, we will resubmit samples of our product to XXXX Labs for analysis, adjusting anything necessary upon the next printing of our labels. A copy of the Lab report and label will be forwarded to you. Our present supply of labels should be used up within 6 – 7 months.
- Regarding the 175 mg of Omega-3 listed on the label – a copy of the XXXX Labs report is enclosed showing the analysis reflected the amount of Omega-3 as stated.

The words ‘high fiber’ will be removed upon the next printing of labels. Our present supply of printed labels will last for 6 to 7 months.

100% Whole Grain Bread

- Regarding the calorie content, total fat, and fiber content, we will resubmit samples of our product to XXXX Labs for analysis, adjusting anything necessary upon the next printing of our labels. A copy of the Lab report and label will be forwarded to you. Our present supply of labels should be used up within 6-7 months.
- Regarding the 300 mg of Omega-3, a copy of XXXX Labs analysis of 100% Whole Grain Bread reflects that the amount of Omega-3 shown on the label is correct.

Sunny Millet Bread

The statement regarding Antioxidants “help prevent...degenerative diseases of all types” will be removed from our label with the next printing. Our present supply of printed labels will last approximately 6 to 7 months.

Health Max Whole Wheat Bread

The statement regarding Antioxidants “help prevent...degenerative diseases of all types” will be removed from our label with the next printing. Our present supply of printed labels will last about 6-7 months.

Ultra Omega Balance Flax Based Supplement with Added Soy

1: FDA Consum 2003 Jan-Feb;37(1):7
New guidelines focus on fish oil, omega-3 fatty acids.

2: Arterioscler Thromb Vasc Biol 2003 Feb 1;23(2):151-2

Omega-3 fatty acids and cardiovascular disease: new recommendations from the American Heart Association.

Kris-Etherton PM, Harris WS, Appel LJ; AHA Nutrition Committee. American Heart Association.

Based on comments and statements in the above two publications and many others a beneficial level of Omega-3 for preventing cardiovascular disease is somewhere between 1 and 3 grams of alpha linolenic acid per day. Since Ultra Omega Balance contains 2 grams of LNA, it seems logical to assume that UOB is a rich source of LNA. I know that regulatory authorities in the US are many years behind Canada and European countries in setting an official RDI level, but this should not prevent people in the US from knowing that UOB is a rich source of Omega-3 and knowledgeable experts in the field would agree with this. The evidence for the other phytochemicals mentioned are about the same.

We erred in using the Nutrition Facts panel. In the next printing, we will use the format for the Supplemental Facts panel.

Enclosed are fatty acid profiles of our products done by [XXXX Labs](#). The circled number indicates the %w/w of alpha linolenic acid in the product. The serving size is 34 grams. If you multiply these two numbers together, multiply by 1000 and divide by 100, you come up with the mg of LNA in one serving of product. If you contact [XXXX Labs](#), I am sure you will find that they are using an approved method of analyzing for linolenic acid. I hope this convinces you that our products contain Omega-3, the common name for alpha-linolenic acid, an essential fatty acid for all mammals. Enclosed are abstracts of scientific articles published just this month on the importance and essentiality of linolenic acid, and the very great importance of banning trans fats from the American food supply.

Please call if you have any questions. We will comply with your requests as quickly as possible.

Respectfully submitted,

Paul A. Stitt, MS Biochemistry

Encl: 7-Grain Bread Label
Fatty Acid Profiles – [XXXX Labs](#)
Scientific articles